

**ReSound® Personal Hearing System EDR-7**

**SUMMARY OF SAFETY AND EFFECTIVENESS**

Substantial equivalence for the ReSound® Personal Hearing System EDR-7 to the predicate device, the ReSound® Personal Hearing System ED3-E, 510(k) No. K950319, February 8, 1995, is based on the following:

- This air-conduction hearing instrument is intended to amplify sound pressure waves and transmit the signal to the external ear through the medium of air to compensate for hearing losses from mild to moderately-severe.
- The device is powered by a standard hearing aid battery (type 13).
- The device is manufactured and delivered completely assembled to the hearing aid dispenser using materials and techniques widely used by other manufacturers of hearing devices.
- The intended use, performance specifications, functions and operations of the ReSound® Personal Hearing System EDR-7 are substantially equivalent to that described in the 510(k) Premarket Notification for the ReSound® Personal Hearing System ED3-E.
- The ability to program digitally the fitting parameters of the hearing device and the ability of the device to retain the program, even when the main battery is removed and changed, is the same as in the ReSound® Personal Hearing System ED3-E. Seven programs are factory preset for the EDR-7 from which the dispenser may select for the fitting. The seven factory preset programs may not be modified by the dispenser via a programmer or by any other means. Modifications in the preset programming may only be accomplished at the factory.